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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,291	10/26/2001	Stephan von Horsten	20488/12 U.S.	9996

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/014,291	<b>Applicant(s)</b> HORSTEN ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-3, 5, 9 and 13 have been amended, claim 8 has been canceled and claims 14-15 have been added as requested in the amendment filed on March 28, 2005. Following the amendment, claims 1-7 and 9-15 are pending in the instant application.

Claims 1-7 and 9-15 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on March 28, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-7 and 9-13, as amended and new claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating anxiety comprising the step of central administration to the central nervous system a therapeutically effective amount of an inhibitor of DP IV enzyme, does not reasonably provide enablement for the same methods wherein said inhibitor is applied to central nervous system by any other routes, including routes specifically recited in claims 6 and 10-13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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Claims 1-7 and 9-15 are directed to methods of treating anxiety by applying to the central nervous system a therapeutically effective amount of an inhibitor of DP IV enzyme. MPEP 2111 [R-1], Claim Interpretation; Broadest Reasonable Interpretation, states

Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given \*>their< broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969).

As such, the broadest reasonable interpretation of the limitation "applying to the central nervous system" in claims 1 and 2 is one of "administration", especially in view of the recitation of routes of "application" as presented in dependent claims 6 and 10-13.

However, it is noted that in traversing the rejection under 35 USC§ 102, see sections IV, VII and VII at pages 7-11 of the Response, Applicant specifically points out that the limitation "applying to the central nervous system" is what distinguishes the instant invention from the prior art of record. Thus, it appears that one of the distinguishing inventive concepts of the instant invention is one of the specific methods of application of inhibitors of DPIV to central nervous system. However, the instant specification, as filed, fails to provide any guidance on how to apply inhibitors of DP IV exclusively to central nervous system with omission of the rest of the body when these inhibitors are applied by inhalation or suppository, for example (see claims 6 and 10-13). There appears to be no references in prior art on how to practice similar

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methods of application or administration. Moreover, the working examples provided in the instant disclosure are limited to the central administration (i.c.v.) (pages 25-33 of the specification) using surgically implanted cannulae.

Thus, in view of the lack of teachings, unpredictability of the art and also the total absence of the working examples, the instant specification is not found to be enabling for the full scope of the claimed methods. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

***Claim Rejections - 35 USC § 102***

6. Claims 2, 7 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. for reasons of record in previous office communications.

Applicant traverses the rejection on the premises that Powers document "does not disclose applying DPIV inhibitors to the "central nervous system" (page 7 of the Response). This argument has been fully considered but is not persuasive because, as fully explained in the previous office actions of record and also in section 5 earlier in the instant office action, the instant claims, as written, encompass application of DPIV inhibitors to central nervous system by inhalation or suppository, which appears to be not limited to the application of the inhibitors exclusively to central nervous system. Therefore, because the claims are broadly drawn to methods of administration of inhibitors of DPIV, document of Powers fully meets the limitations of the instant claims.

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7. Claims 1, 3-4, 6, 9 and 11-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. for reasons of record in previous office communications.

To traverse this rejection, Applicant argues again that Powers document does not disclose applying DPIV inhibitors to the central nervous system (pages 8-9 of the Response). This argument has been fully considered but is not persuasive for reasons of record in section 6 of the instant office action.

8. Claims 1-4, 6, 7, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Demuth et al., for those reasons of record in previous office communications.

Applicant submits that “Demuth ‘893 is completely devoid of any disclosure related to DP-IV inhibitors for the treatment of central nervous system disorders through the use of DP IV inhibitors by “applying to the central nervous system” (middle at page 10 of the Response). This argument is fully considered but is not persuasive for reasons of record fully explained in section 6 of the instant office action.

### ***Double Patenting***

9. Claims 1-4, 6, 7, 9-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,319,893 for reasons of record in previous office communications.

### ***Conclusion***

10. No claim is allowed.

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11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original

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signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1646

May 4, 2005